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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/577,059	05/22/00	CURATOLO	W PC8626BJTJ

EXAMINER	
DEWITTY,R	
ART UNIT	PAPER NUMBER
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DATE MAILED:
06/04/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/577,059	Applicant(s) CURATOLO ET AL.	
	Examiner Robert M DeWitty	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *72-148* is/are pending in the application.

4a) Of the above claim(s) *77-79,87-92,130-132 and 140-145* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *72-76, 80-86, 93-129, 133-139, and 146-148* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Claims 72-76, 80-86, 93-129, 133-139, and 146-148 are pending in the instant application.

Claims 77-79, 87-92, 130-132, 140-145 are withdrawn as being drawn to non-elected species.

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species of the claimed invention: a matrix which can comprise hydroxypropyl methylcellulose, hydroxypropyl cellulose, poly(ethylene oxide), or polyacrylic acid; a dosage form in the form of a multiparticulate, or a tablet; a dosage form in the shape of a cylinder, a cone, a hemisphere, a half-cylinder or a coated bi-layer tablet; an uncovered area in the form of a passageway, a slit, or a open area.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 72, 75, 83, 96, 97, 100, 104, 118,119, 125, 126, 128, and 136 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

1. During a telephone conversation with James T. Jones on 4/1/01 a provisional election was made with traverse to the species hydroxypropyl methylcellulose, a tablet, a cylinder, and a coated tablet. Affirmation of this election must be made by applicant in replying to this Office action. Claims 77-79, 87-92, 130-132, 140-145 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 72-76, 80-86, 93-130, 133-139, and 146-148 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al., further in view of Handsfield et al., and Lee and Robinson.

Curatolo et al. (U.S. Pat. No. 5,605,889) teaches a dosage form of azithromycin Which can be administered to a mammal. The dosage form is composed of from about 25mg to 3 grams of azithromycin (col. 4, lines 51-54). The dosage forms can further be adjusted depending on the size of the animal subject being treated (Id. at lines 54-57). During in-vitro analysis utilizing USP-2 dissolution apparatus under the conditions of 900ml approx. 0.1M dibasic sodium phosphate buffer, pH 6.0, 37°C, with paddles turning at 100rpm, the azithromycin dosage form of Curatolo et al. exhibits 90% dissolution within 15 minutes when an amount of the dosage form is equivalent to 200mg (col. 5, lines 27-35). When comparing dosage forms of different types, in vitro dissolution rates should correlate with in vivo dissolution rates (col. 5, lines 57-60). It is further taught that tablet blends of the dosage form maybe dry or wet granulated before tableting (col. 7, lines 51-52), such granules dried, blended and pressed to make the dosage form (see Example 8, col. 16). The tablet blends can be film-coated with hydroxypropylmethylcellulose (col. 7, line 65-col. 8, line 2).

Handsfield et al. ("Single-dose azithromycin versus ceftriaxone for treatment of uncomplicated gonorrhea") teaches that 2.0 grams of azithromycin administered for treatment of uncomplicated gonorrhea, cured 41/41 men and 4/4 women, however caused nausea in 34% and diarrhea in 14% (see abstract).

It is taught in the prior art, as shown by Urquhart et al. (U.S. Pat. No. 4,851,231), that certain drugs should not be administered to the stomach, for example drugs that are digested or decomposed in the acidic environment of the stomach such as the antibiotic erthromycin and drugs that induce nausea and vomiting (col. 1, lines 38-43). Urquhart et al. teaches the need for a delivery system which avoids administering a drug in the stomach, but rather administers a drug in a therapeutically effective amount in the intestine over time (col. 1, lines 58-63).

Edgren (U.S. Pat. No. 4,522,625) teaches a dispenser for releasing drug formulations in the gastrointestinal tract. The dispenser of Edgren allows for the delivery of drugs at rates precisely controlled by the dispenser, which are rates in response to the biological environment (col. 1, lines 44-51). The dispenser is comprised of a body having a wall that surrounds an internal compartment. A passageway in the wall connects the interior of the dispenser with the exterior (col. 2, lines 39-47). The dispenser can be made for oral use, such use being useful for releasing in the gastrointestinal tract either a locally or systemically acting drug over a prolonged period of time (col. 3, lines 43-46). The oral dispenser can have various shapes such as round or capsule shaped (Id. at lines 48-49).

Enteric materials can be blended with a semi-permeable polymer for forming the wall of the dispenser, such enteric materials including hydroxypropyl methylcellulose phthalate (col. 4 lines 35-37 and lines 64-65). The passageway includes apertures, orifices, bores, holes, and the like through the wall (col. 5, lines 32-34). The expression drug can include antibiotics such as erythromycin (col. 5, line 66 and col. 6, line 4).

As the above art was available at the time the invention was made, a delayed release drug comprising 2 g of azithromycin for dispense within 6 hours would have been known to one of ordinary skill in the art. One with ordinary skill would have been motivated to use 2 g of azithromycin in a single dose in order to obtain the beneficial effects of using such a dosage amount (*see* Handsfield, (41/41 men and 4/4 women cured). Because the harmful effects of 2 g of administered azithromycin were known (nausea and diarrhea), one with ordinary skill would have been motivated to administer such dosage in the gastrointestinal tract as opposed to the stomach. This could have been accomplished by using a controlled release dosage form that aids in delivering drugs at a rate in conjunction with the environment (the gastrointestinal tract). As azithroymycin is a known antibiotic and derivative of erythromycin, one with ordinary skill would have been motivated to use azithroymycin in such a controlled release dosage form. Still yet, because the delayed delivery dosage form of azithroymycin would have been like the delivery dosage form of the instant invention, the dissolution rates using a USP rotating paddle apparatus are inherent.

Thus, the above claims are made obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone number for the organization where this application or proceeding is assigned is 703-308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD
May 29, 2001

JOSE G. DEES
SUPERVISORY PATENT EXAMINER
1616